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| (54) Title: NUTRITIONAL SUPPLEMENT COMPOSITION AND USE | | |
| (57) Abstract <p>The present invention relates to nutritional supplements to the human diet used to increase levels of high density lipoprotein (HDL) and calcium ions, and decrease levels of free radicals and glucose in human blood plasma. More specifically, the present invention teaches novel nutritional supplements which comprise a first class of compositions that contain a novel combination of: (1) a specific antioxidant composition; (2) a specific green barley composition; (3) a specific vitamin and mineral composition, and (4) a particular tincture of ginkgo biloba extract, as well as methods of preparing the nutritional supplements. In addition, the present invention comprises a second class of compositions that contain a novel combination of vitamins A, E, C, selenium, and specific juice concentrates, as well as methods of preparing these nutritional supplements.</p> | | |

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NUTRITIONAL SUPPLEMENT COMPOSITION AND USE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to nutritional supplements
5 to the human diet, and more specifically to nutritional
supplements which contain a combination of naturally occurring
substances such as vitamins and minerals, antioxidants, green
barley extract, and ginkgo biloba extract.

2. Background

10 Diets complete in nutritional substance are important for
the human body in order to afford consistent high levels of
optimum performance, both in cognitive ability and physical
health. Although the exact needs of the human species to
develop and maintain peak performance on a daily basis and
15 sustain such for the duration of the human life are not
completely understood, it is widely recognized that
maintaining balanced nutrition coupled with sensible levels of
daily exercise are the fundamental bases for optimizing the
condition of the human body. It is also widely accepted that
20 the risk of many common ailments from environmental sources or
many ailments arising from genetic consequences can be reduced
through the daily practice of, in addition to exercise, a
complete nutritional regime fortified with certain vitamins,
minerals, food and herb concentrates, especially, in the case
25 of certain genetic consequences, during the antenatal period.
Increased human longevity is understood to be a potential
consequence of these daily practices.

Cardiovascular disease resulting from the buildup of arterial plaque is a leading cause of illness or death. Arterial plaque is precipitous material formed chiefly of oxidized low density lipoprotein (O-LDL). The buildup of plaque in the form of O-LDL in the arteries is understood to be a factor in ischaemic heart disease. Free radical oxidants, many of which come from naturally occurring sources such as sun exposure, metabolism of certain nutrients, and exercise, act to oxidize low density lipoprotein (LDL) into its deleterious form, O-LDL. Hence, free radical "scavengers" such as vitamins A, E, C, and selenium are believed to react with these oxidants so that they are not available to form O-LDL, thus lowering the risk of arterial plaque deposits in blood vessels. In contrast, the presence of high density lipoprotein (HDL) in the body is understood to have beneficial health effects. Specifically, HDL is known to be a more soluble form of lipoprotein; hence its presence does not significantly contribute to the formation of arterial plaque. In addition, it is known that HDL is able to absorb plaque material and may thus directly reduce the amount of arterial plaque.

3. Description of the Background Art

Certain vitamins and minerals, antioxidants, and plant extracts are generally known to have beneficial health effects. For example, several beneficial aspects of antioxidants have been known for many years. Antioxidants are chemicals that react with free radicals, such as hydroxy

radical, to protect certain biological systems. The removal of free radicals from the body has been suggested to increase human longevity -- specifically, the presence of antioxidants including superoxide dismutase (SOD), carotenoids, alpha-tocopherol, and uric acid is suggested to have a positive correlation with resistance to spontaneous autoxidation of tissues and oxidative damage to DNA in mammals [Cutler, R., Am. J. Clin. Nutr., 53:373S-9S (1991)]. Antioxidants are also known to limit destruction of healing brain tissue by free radicals as shown by the method for resuscitating the brain using vitamins such as A, E and C or selenium [See, Klatz et al., U.S. Patent No. 5,149,321 and PCT application PCT/US92/06681].

In addition to their antioxidant activity, vitamins A, C, and E are well known to have other beneficial health effects. For example, vitamin E is known to help maintain proper blood sugar levels. As another example, vitamin C is known to play an integral role in the integrity of connective and structural tissues in the body. Vitamin A is known to play a role in maintaining good vision as well as in growth and development. Hence, an adequate supply of these vitamins is essential in maintaining optimum health. The use of vitamins A, E, C and selenium has been proposed as a means to inhibit or prevent collagen cross-linking in human skin when used in combination with certain active peptides [See, Geoffrey et al., PCT application WO 90/06102].

Green barley is known to be a rich source of highly metabolizable vitamins and minerals such as vitamins A, B1,

B2, B6, and C, potassium, magnesium, and zinc. In addition, green barley also has a high concentration of the enzyme superoxide dismutase (SOD), which has been shown to have high levels of antioxidant activity. Green barley is believed to be an important nutrient in the regulation of the digestive process because the micronutrients, enzymes (e.g., SOD), and fiber contained in green barley are believed to improve intestinal function [D. Walsh et al., British J. Nutr., 70:621-630 (1993)].

Ginkgo biloba has been a staple Chinese herbal ingredient for thousands of years, and is frequently recommended by Chinese herbal practitioners for coughs, asthma and acute allergic inflammations. There are many active organic compounds in ginkgo biloba, including Ginkgolide B which has been shown to be an active constituent and which apparently works by interfering with platelet activating factor (PAF). PAF is known to have several biological functions, including induction of platelet aggregation, neutrophil degranulation and oxygen radical production, and increasing microvascular permeability and bronchoconstriction. It has been shown that by its inhibitory interaction with PAF, Ginkgolide B helps improve cerebral metabolism and protect the brain against hypoxic damage in laboratory animals with cerebral ischaemia [Kleijnen, J. and Knipschild, P., The Lancet, 340:1136-39 (1992)]. In addition, ginkgo biloba extract is licensed in Germany for the treatment of cerebral dysfunction, hearing loss resulting from cervical syndrome, and peripheral arterial circulatory disturbances with intact circulatory reserve

(intermittent claudication) [See, Kleijnen, J. and Knipschild, P., cited above]. Other studies indicate the efficacy of using ginkgo biloba extract to improve mental acuity [See, e.g., Nutrition Today, July/August:11-18 (1988); Ginkgo Biloba Extract in Perspective, Auckland, New Zealand: ADIS Press Limited:1ff (1990)].

A healthy balance of vitamins and minerals has been known to be critical to sustain a healthy human body. Many combinations of vitamins and minerals have been taught over the years as food supplements beneficial to a human health, and the daily ingestion of fruits and vegetables has long been recognized as critical to a healthy diet.

There remains a need in the art for novel daily food supplements that provide high levels of antioxidant activity, and thereby increase cardiovascular fortitude, maintain proper blood sugar balance, support mental awareness and intellectual performance, reduce the risk of digestive problems, and strengthen connective and structural tissues.

SUMMARY OF THE INVENTION

The compositions of the present invention are novel combinations of selected ingredients that are known to benefit the human organism. More particularly, a first class of nutritional supplements of the present invention provides a novel combination of: (1) a specific antioxidant component; (2) a specific green barley component; (3) a specific vitamin and mineral component, and (4) a particular tincture of ginkgo biloba extract, the combination of which provides for improved

nutrition when ingested by humans. A second class of nutritional supplements of the present invention provides a novel combination of ingredients of the antioxidant component, the combination of which provides for improved nutrition when ingested by humans.

It is therefore an object of the invention to provide a first class of novel compositions containing a combination of: (1) a specific antioxidant component; (2) a specific green barley component; (3) a specific vitamin and mineral component, and (4) a particular tincture of ginkgo biloba extract. It is another object to provide a second class of nutritional supplement compositions containing a novel combination of ingredients of the antioxidant component.

The present invention also teaches the use of these compositions to supplement the human diet. Therefore, it is an object of the invention to provide novel a method of supplementing the human diet using the dietary supplements taught herein.

It is a further object of the present invention to provide a method of preparing the nutritional supplements of the present invention.

It is yet another object of the present invention to provide nutritional supplements to safely reduce the risk of health problems arising from the presence of free radicals and other oxidants in human blood and tissues.

In still another object, the present invention provides for methods to maintain proper glucose levels in blood serum using the novel nutritional supplements of the invention.

Another object of the present invention is to increase levels of minerals such as calcium in human blood serum and tissues using the novel nutritional supplements of the present invention.

5 Another object of the present invention is to increase levels of vitamins such as vitamins A and E and other nutrients such as beta-carotene in human blood serum and tissues using the novel nutritional supplements of the present invention.

10 In a further object, the present invention provides methods for reducing the risk of the harmful biological effects of free radicals and other oxidants in the human system.

In still a further object, the present invention provides
15 novel nutritional supplements used to effect memory enhancement.

DETAILED DESCRIPTION OF THE INVENTION

The novel nutritional compositions of the present invention significantly improve the general metabolic,
20 circulatory and nervous systems of the human body, and thus help overcome, or diminish the effect of many of the metabolic problems that occur with the aging of the human system. The present compositions are novel combinations of naturally occurring substances, are non-toxic when administered
25 according to the methods of the present invention, and provide for a more complete nutritional regime.

The present invention focuses on the development and maintenance of vitality and fortitude of the human body as a direct result of the daily oral intake of the compositions of the present invention. The aim of the present invention is to provide compositions that act on the human systems to safely reduce the risks of health problems arising from the presence of oxidants in the human blood and tissues, from low glucose levels in blood serum, and from inadequately low levels of minerals such as calcium in the human blood serum and tissues. Helping avoid the harmful biological effects of free radicals in the human system, namely inflammation, collagen degradation, and cardiovascular disease, among others, is a prime objective of the present invention. The present invention also provides a composition and method that may maintain proper blood sugar levels and effect memory enhancement.

Some of the observable metabolic changes effected as a direct result of administering the compositions of the present invention are significant, and include: (a) a significant lowering of the blood sugar level; (b) an increase in the concentration of high density lipid protein (HDL) in the blood serum; (c) an increase in blood serum calcium levels, and (d) an increase in blood serum levels of nutrients known to improve human health such as vitamins A and E, and beta-carotene.

Evidence of the effect of the compositions of the invention on calcium ion concentrations and blood glucose levels may be seen in the Examples below. For humans, a

normal blood glucose level is approximately 100 mg/dl. It is generally understood that persons having a blood glucose level of between 100 mg/dl and 150 mg/dl have above-normal levels, and individuals having a blood glucose level of greater than 150 mg/dl are considered diabetic. Since the compositions of the present invention are able to cause an approximate 22% decrease in the level of blood glucose, individuals who have above normal levels of blood glucose may have their levels reduced to normal levels upon administration of the compositions of the present invention.

The compositions of the present invention are also believed to have an effect on memory enhancement because they contain ginkgo, a substance known to have an effect on persons suffering from difficulties of concentration and memory, absent mindedness, confusion, and headaches [See, Kleijnen, J. and Knipschild, P., cited above].

The compositions of the present invention represent a combination of nutritive food supplements that work together with various metabolic systems of the human body. Each composition in a first class of novel nutritional supplement compositions contains at least one of each of the following four components: (1) a compendial grade multi-vitamin and mineral dietary supplement, where a primary source of the vitamins is from specific combinations of food concentrates; (2) a green barley extract; (3) a compendial grade of a specified combination of antioxidant vitamins A, C, E, and selenium, where the primary source of the antioxidants arises from selected food concentrates which may or may not be the

same as the selected food concentrates of the multi-vitamin and mineral component; and (4) a ginkgo biloba extract. Each of these four components is processed separately, in a pharmaceutically acceptable manner, either as solid powder, tablets, lozenges, pills, capsules, or in liquid forms, and may be administered separately or in suitable combinations with other components, including, for example, being combined into a single preparation for administration. More specifically, the first class of compositions of the present invention can be administered as: (1) a dosage comprising multiple lozenges of separate and distinct components (e.g., a green barley extract component, an antioxidant component, a multi-vitamin and mineral component, and a ginkgo biloba extract component), or, more preferably; (2) a dosage comprising multiple lozenges, each of the same composition, where the four components are combined into a single lozenge; or (3) other dosage forms known in the art. Each of the vitamins and minerals as well as the ginkgo biloba and green barley extracts of the components are commercially available, and can be blended to form a single composition or can form multiple compositions which may be co-administered.

A summary of the ingredients of the food concentrates and their respective antioxidant element(s) is provided in Table I.

TABLE I

| Component | Vitamins and Minerals | Antioxidant Element |
|--------------|---|---------------------|
| Acorn Squash | Potassium, Calcium, Phosphorus, Vitamin B1, B2, C | Vitamin C |

| | | |
|------------------|---|----------------------------|
| Alfalfa | Vitamins A, B1, B2, B6, C, E, K, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc | Vitamins A, C, E |
| Apple | Potassium, Manganese, Cobalt, Molybdenum, Phosphorus, Vanadium, Vitamins A, B1, B2, C, Folic acid | Vitamins A, C |
| Artichoke | Vitamins A, B1, B2, B6, C, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc | Vitamins A, C |
| Avocado | Vitamin A, Calcium, Phosphorus, Iron, Potassium, Sodium, Thiamine, Riboflavin, Niacin, Ascorbic acid | Vitamin A |
| Bananas | Vitamin A, Calcium, Phosphorus, Iron, Potassium, Sodium, Thiamine, Riboflavin, Niacin, Ascorbic acid | Vitamin A |
| Broccoli | Potassium, Magnesium, Calcium, Phosphorus, Vitamins A, E, C, B1 | Vitamins A, C, E |
| Brussels Sprouts | Potassium, Magnesium, Calcium, Copper, Phosphorus, Selenium, Vitamins A, E, C, B2, Folic acid | Vitamins A, E, C, Selenium |
| Cabbage | Vitamins A, B1, B2, C, Niacinamide, Folic acid, Calcium, Iron, Magnesium, Potassium, Phosphorous | Vitamins A, C |
| Cantaloupe | Vitamin A, Calcium, Phosphorus, Iron, Potassium, Sodium, Thiamine, Riboflavin, Niacin, Ascorbic acid | Vitamin A |

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| | | |
|----------------|--|----------------------------|
| Carrot | Vitamins A, B1, B2, B6, C, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc | Vitamins A, C |
| Cauliflower | Potassium, Magnesium, Calcium, Phosphorus, Vitamins A, E, K, C, Folic acid | Vitamins A, C, E |
| Celery | Potassium, Iron, Calcium, Phosphorus, Vitamins A, E, K, C, Folic acid | Vitamins A, C, E |
| Collard Greens | Potassium, Magnesium, Calcium, Vitamins A, C | Vitamins A, C |
| Grapefruit | Vitamins A and C, Calcium, Phosphorus, Iron, Potassium, Sodium, Thiamine, Riboflavin, Niacin, Ascorbic acid | Vitamins A, C |
| Green Leek | Potassium, Calcium, Copper, Phosphorus, Vitamins E, B2, C | Vitamins E, C |
| Green Barley | Vitamins A, B1, B2, B6, C, K, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc, Superoxide Dismutase (SOD) | Vitamins A, C, SOD |
| Kale | Potassium, Magnesium, Calcium, Chromium, Selenium, Vitamins A, E, C | Vitamins A, C, E, Selenium |
| Kiwi Fruit | Potassium, Magnesium, Calcium, Phosphorus, Vitamins A, C, B1, B2 | Vitamins A, C |
| Lettuce | Potassium, Magnesium, Calcium, Vitamins A, E, C, B1, B2, Folic acid | Vitamins A, C, E |

| | | |
|--------------|--|-------------------------|
| Onion | Potassium, Magnesium, Calcium, Copper, Cobalt, Chromium, Vanadium, Phosphorus, Selenium, Vitamins A, B1, B2, C, Biotin, Folic acid | Vitamins A, C, Selenium |
| Papaya | Vitamins A, B1, B2, B6, C, Niacinamide, Pantothenic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc | Vitamins A, C |
| Parsley | Vitamins A, B1, B2, B6, C, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc, Para aminobenzoic acid (PABA) | Vitamins, A, C |
| Potato | Potassium, Vitamins A, B2, C, K, E, Folic acid, Phosphorus, Iodide, Calcium, Chromium | Vitamins A, C, and E |
| Prune | Vitamin A, Calcium, Phosphorus, Iron, Potassium, Sodium, Thiamine, Riboflavin, Niacin, Ascorbic acid | Vitamin A |
| Spinach | Vitamins A, B1, B2, B6, C, E, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc | Vitamins A, C, E |
| Strawberry | Vitamins A, B1, B2, B6, C, Niacinamide, Pantothenic acid, Folic acid, Calcium, Copper, Iron, Magnesium, Manganese, Potassium, Phosphorous, Zinc | Vitamins A, C |
| Sweet Potato | Potassium, Vitamins B1, B2, C, Folic acid, Phosphorus, Selenium, Calcium | Vitamin C, Selenium |

| | | |
|-------------|---|----------------------------|
| Swiss Chard | Potassium, Magnesium, Calcium, Vitamins A, C | Vitamins A, C |
| Tomato | Potassium, Magnesium, Calcium, Nickel, Chromium, Phosphorus, Boron, Selenium, Vitamins A, C, K, B1, B2, Folic acid | Vitamins A, C, Selenium |

I. First Class of Nutritional Supplements

A. Antioxidant Component

5 As a preferred embodiment, a dosage of the antioxidant component of the first class of nutritional supplement compositions of the present invention may consist of two lozenges for human oral consumption. In such an embodiment, the preferred weight of each of the antioxidant lozenges is
10 between about 1,000 mg to about 2000 mg, and preferably about 1,500 mg. The total weight of one dosage of the antioxidant component of the present invention is between about 2,000 mg and about 4,000 mg, and most preferably about 3,000 mg. The antioxidant lozenge comprises vitamins A, E, C, and selenium,
15 and at least one juice concentrate, selected from the plurality of juice concentrates including acorn squash, alfalfa, apple, artichoke, avocado, bananas, broccoli, brussels sprouts, cabbage, cantaloupe, carrot, cauliflower, celery, collard greens, grapefruit, green leek, green barley,
20 kale, kiwi fruit, lettuce, onion, papaya, parsley, potato, prune, spinach, strawberry, sweet potato, swiss chard, and tomato juice concentrates.

 The total weight of the combination of vitamin C, vitamin A, vitamin E, and selenium in the antioxidant component of the
25 present invention is about 10% to about 50% of the total

weight of the antioxidant lozenge, preferably about 15% to about 30% of the total weight of the antioxidant lozenge and most preferably about 20% of the total weight of the antioxidant lozenge.

5 A suitable antioxidant component consistent with the present invention comprises about 5,000 IU to about 20,000 IU of vitamin A, more preferably about 7,500 IU to about 15,000 IU and most preferably about 9,000 IU to about 10,000 IU of vitamin A (in the form of beta-carotene) per dose.

10 A compendial grade of vitamin C can be employed in the antioxidant component of the present composition. The antioxidant component comprises, by weight percent, about 200 mg to about 2,000 mg of vitamin C, preferably about 300 mg to about 1,000 mg of vitamin C and most preferably about 450 mg
15 to about 550 mg per dose.

 A compendial grade of vitamin E can also be employed in the antioxidant component of the present composition. The antioxidant component comprises about 100 IU to about 500 IU of vitamin E, preferably about 175 IU to about 425 IU of
20 vitamin E, and most preferably about 190 IU to about 225 IU of vitamin E per dose.

 A compendial grade of selenium can be incorporated in the antioxidant component of the present invention. The antioxidant component of the present invention comprises, by
25 weight, about 50 micrograms to about 200 micrograms of selenium, preferably about 75 micrograms to about 150 micrograms, and most preferably about 100 micrograms of selenium per dose.

The total weight of the juice concentrates in the preferred embodiment of the antioxidant component of the present invention is about 30 to about 80% of the total weight of the antioxidant lozenge, and most preferably about 60% of the weight of the antioxidant lozenge.

A suitable composition consistent with the present invention comprises juice concentrates having a concentration of at least 10 times that of the native juice in the unconcentrated form, and preferably about 15 times more concentrated, and most preferably about 20 times more concentrated than the unconcentrated juice. In concentrated form, the juice concentrates are essentially anhydrous, and are generally in powder form.

When present, a form of acorn squash suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of alfalfa juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of apple juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of artichoke juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

When present, a form of avocado juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 1% of the weight of the juice concentrate composition of the present invention.

When present, a form of banana juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 1% of the weight of the juice concentrate composition of the present invention.

When present, a form of broccoli juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of brussels sprout juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of cabbage juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 1% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

When present, a form of cantaloupe juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5%

to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of carrot juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of cauliflower juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of celery juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of collard greens juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about

1% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

5 When present, a form of grapefruit juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about
10 2% of the weight of the juice concentrate composition of the present invention.

 When present, a form of green leek juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about
15 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

 When present, a form of green barley juice suitable for
20 use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the
25 weight of the juice concentrate composition of the present invention.

 When present, a form of kale juice suitable for use to supplement the human diet that can be used in the antioxidant

component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 1% of the weight of the juice concentrate composition of the present invention.

When present, a form of kiwi fruit juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 1% of the weight of the juice concentrate composition of the present invention.

When present, a form of lettuce juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 1% of the weight of the juice concentrate composition of the present invention.

When present, a form of onion juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 5% of the weight of the juice concentrate composition of the present invention.

When present, a form of papaya juice suitable for use to supplement the human diet that can be used in the antioxidant

component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of parsley juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of potato juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of prune juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of spinach juice suitable for use to supplement the human diet that can be used in the antioxidant

component of the present invention comprises about 5% to about 25% of the weight of the total juice concentrate compound of the present invention, more preferably about 7.5% to about 15%, and most preferably about 8% to about 12% of the weight of the juice concentrate composition of the present invention.

When present, a form of strawberry juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 7.5% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

When present, a form of sweet potato juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

When present, a form of swiss chard juice suitable for use to supplement the human diet that can be used in the antioxidant component of the present invention comprises about 0.5% to about 7.5% of the weight of the total juice concentrate compound of the present invention, and most preferably about 2% of the weight of the juice concentrate composition of the present invention.

When present, a form of tomato juice suitable for use to supplement the human diet that can be used in the antioxidant

component of the present invention comprises about 1% to about 10% of the weight of the total juice concentrate compound of the present invention, and most preferably about 3% of the weight of the juice concentrate composition of the present invention.

B. Multi-Vitamin and Mineral Component

In a preferred embodiment, the multi-vitamin and mineral component of the first class of compositions of the present invention consists of two multi-vitamin and mineral lozenges for human oral consumption taken twice daily (total of four lozenges per day -- i.e., two doses per day). The preferred weight of each of the lozenges is between about 750 mg to about 1,500 mg, preferably about 1,000 mg. The total weight of one dosage of the vitamin-mineral component of the present invention is between about 1,500 mg and about 3,000 mg and most preferably about 2,000 mg.

The multi-vitamin and mineral component of the first class of compositions of the invention may be comprised of juice concentrates -- the total weight of which is about 4% to about 25% the total weight of the multi-vitamin and mineral lozenge, and most preferably about 12% of the weight of the multi-vitamin and mineral lozenge. When the first class of nutritional supplement is administered as a single lozenge, the total weight of the juice concentrate is about 3% to about 50%, and most preferably about 5% to about 35% of the total weight of the lozenge.

The total weight of the combination of non-juice concentrate-derived vitamins and minerals in the multi-vitamin component of the first class of compositions of the present invention is about 10% to about 90% of the total weight of the multi-vitamin and mineral lozenge, preferably about 15% to about 80% of the total weight of the multi-vitamin and mineral lozenge and most preferably about 65% of the total weight of the multi-vitamin and mineral lozenge.

In a preferred embodiment, a suitable multi-vitamin and mineral component of the first class of compositions of the present invention comprises about 1,000 IU to about 10,000 IU of vitamin A, more preferably about 1,500 IU to about 4,500 IU and most preferably about 3,500 IU of vitamin A (in the form of beta-carotene) per lozenge. Vitamin A may be contributed by the juice concentrates as described above, or it may be contributed in non-juice form.

In a preferred embodiment, a compendial grade of vitamin C can be employed in the multi-vitamin composition. Each lozenge of the multi-vitamin component of the first class of compositions of the present invention comprises, by weight, about 10 mg to about 200 mg of vitamin C, preferably about 15 mg to about 175 mg of vitamin C and most preferably about 125 mg per lozenge. Vitamin C may be contributed by the juice concentrates as described above, or it may be contributed in non-juice form.

In a preferred embodiment, a suitable multi-vitamin component of the first class of compositions of the present invention comprises about 10 IU to about 1,000 IU of

vitamin D, more preferably about 15 IU to about 350 IU and most preferably about 100 IU of vitamin D per lozenge.

A suitable multi-vitamin component of the first class of compositions of the present invention comprises about 5 IU to
5 about 50 IU of vitamin E, more preferably about 5 IU to about 35 IU and most preferably about 11.5 IU of vitamin E per lozenge. Vitamin E may be contributed by the juice concentrates as described above, or it may be contributed in non-juice form.

10 In a preferred embodiment, a compendial grade of folic acid or folic acid salt may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention comprises, by weight, about 0.03 mg to about 1 mg of folic acid, preferably about 0.04 mg to about 0.06 mg
15 of folic acid, and most preferably about 0.05 mg of folic acid per lozenge.

In a preferred embodiment, a compendial grade of thiamine (B-1) may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present
20 invention comprises, by weight, about 0.01 mg to about 1.0 mg of thiamine (B-1), preferably about 0.15 mg to about 0.75 mg of thiamine (B-1) and most preferably about 0.5 mg of thiamine (B-1) per lozenge.

In a preferred embodiment, a compendial grade of
25 riboflavin may be employed in the multi-vitamin composition. Each lozenge of the multi-vitamin composition of the present invention comprises, by weight, about 0.01 mg to about 5.0 mg of riboflavin, preferably about 0.15 mg to about 2.75 mg of

riboflavin and most preferably about 0.5 mg of riboflavin per lozenge.

In a preferred embodiment, a compendial grade of niacin may be employed in the multi-vitamin component. Each lozenge
5 of the multi-vitamin component of the present invention comprises, by weight, about 1.0 mg to about 100 mg of niacin, preferably about 0.5 mg to about 10 mg of niacin and most preferably about 7.5 mg of niacin per lozenge.

In a preferred embodiment, a compendial grade of
10 vitamin B-6 may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention comprises, by weight, about 1.0 mg to about 10.0 mg of vitamin B-6, preferably about 1.5 mg to about 7.5 mg of vitamin B-6 and most preferably about 1.125 mg of vitamin B-6.

15 In a preferred embodiment, a compendial grade of vitamin B-12 may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention comprises, by weight, about 1.0 mg to about 10.0 mg of vitamin B-12, preferably about 1.5 mg to about 7.5 mg of
20 vitamin B-12 and most preferably about 2.25 mg of vitamin B-12.

In a preferred embodiment, a compendial grade of biotin may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention
25 comprises, by weight, about 0.10 mg to about 1.00 mg of biotin, preferably about 0.15 mg to about 0.95 mg of biotin and most preferably about 0.75 mg of biotin.

In a preferred embodiment, a compendial grade of zinc may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention comprises, by weight, about 1.0 mg to about 10.0 mg of zinc, preferably about 1.5 mg to about 7.5 mg of zinc and most preferably about 5.0 mg of zinc.

In a preferred embodiment, a compendial grade of manganese may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention comprises, by weight, about 1.0 mg to about 10.0 mg of manganese, preferably about 1.15 mg to about 1.75 mg of manganese and most preferably about 1.25 mg of manganese.

In a preferred embodiment, a compendial grade of selenium may be employed in the multi-vitamin component. Each lozenge of the multi-vitamin component of the present invention comprises, by weight, about 5 micrograms to about 20 micrograms of selenium, preferably about 7.5 micrograms of selenium.

In a preferred embodiment, a suitable multi-vitamin and mineral component of the first class of compositions of the present invention optionally comprises juice concentrates having a concentration of at least 10 times that of the native juice in the unconcentrated form, and preferably about 15 times more concentrated, and most preferably about 20 times more concentrated than the unconcentrated juice. In concentrated form, the juice concentrates are essentially anhydrous, are generally in powder form, and may be selected from the juice concentrates of the antioxidant component.

C. Green Barley Component

In a preferred embodiment, the green barley component of the first class of compositions of the present invention comprises, by weight percent, about 60% to about 90%, and most preferably about 80% green barley juice concentrate [Westar Nutrition, Inc.]. A preferred green barley preparation of the present invention consists of one lozenge (one dose) twice per day for human consumption. A preferred weight of the green barley lozenge is from about 600 mg to about 1,000 mg and most preferably about 750 mg. This green barley component of the first class of compositions of the compositions of the present invention is a separate required component from the green barley juice concentrate that may exist as part of the antioxidant preparation. This green barley component, although separate and required, may take the same form as that described in the antioxidant section above.

D. Ginkgo Biloba Component

The ginkgo biloba extract component of the first class of compositions of the present invention consists of about 5% to about 35% and most preferably from about 10% to about 15% ginkgo biloba extract [Westar Nutrition, Inc.]. A preferred dosage of the ginkgo biloba extract component of the present invention consists of one lozenge twice a day for human consumption. A preferred weight of the lozenge is from about 400 mg to about 750 mg, and most preferably 500 mg.

E. Dosage of the First Class of Nutritional Supplements

A preferred dosage of the first class of compositions of the present invention may consist of six lozenges for human oral consumption -- two antioxidant lozenges, two vitamin and mineral lozenges, and one of each of the ginkgo biloba extract and green barley extract lozenges. The preferred weight of each of the antioxidant and vitamin and mineral lozenges is between about 1,000 mg to about 2,000 mg, preferably about 1,500 mg. The preferred weight of the green barley lozenge is about 600 mg to about 1,000 mg, and preferably about 750 mg. The preferred weight of the ginkgo biloba lozenge is about 400 mg to about 750 mg, and most preferably about 500 mg. The total weight of one dosage of the first class of compositions of the present invention is between 6,000 mg and 12,000 mg and most preferably about 9,000 mg. Alternatively, the components of the first class of compositions of the present invention may be combined into fewer than six lozenges to give the appropriate amounts of each component. In a preferred embodiment, a dosage is administered twice daily.

II. Second Class of Nutritional Supplements

In a second class of compositions of the present invention, select moieties of the antioxidant component of the first class of compositions of the present invention may provide for many of the beneficial health effects described above. Specifically, the second class of compositions may consist of two lozenges for human oral consumption. The second class of compositions of the present invention falls within the description of the antioxidant component of the

first class of compositions described above, but it is as specific combination of the ingredients of that component. More specifically, the second class of compositions comprises a novel combination of vitamins A, E, C, and selenium, and a mixture of alfalfa, artichoke, cabbage, carrot, green leek, green barley, papaya, parsley, spinach, and strawberry juice concentrates.

Similar to the first class of nutritional supplements described above, the second class of compositions of the present invention may be administered in two antioxidant lozenges. The preferred weight of each of the antioxidant lozenges is between about 1,000 mg to about 2000 mg, and preferably about 1,500 mg. The total weight of one dosage of the second class of compositions of the present invention is between about 2,000 mg and about 4,000 mg, and most preferably about 3,000 mg.

The vitamin A, E, C, selenium, and juice concentrate components of the second class of nutritional supplements of the present invention are the same as those described for the first class of compositions, both in terms of amounts used in the antioxidant lozenges and with respect to the sources of those components. Since the second class of compositions of the present invention falls within the description of the antioxidant component of the first class of compositions, it is understood that the first and second classes of nutritional supplement compositions are different aspects of the same nutritional supplement invention disclosed herein.

III. Preparation of the Nutritional Supplements of the Invention

To prepare the components of the invention from either class of compositions, the active ingredients are blended in intimate admixture with a suitable carrier according to conventional compounding techniques. Alternatively, each of the active ingredients for any or each of the four components may be combined in intimate admixture with a suitable carrier according to conventional compounding techniques. This carrier may take a wide variety of forms depending upon the form of preparation desired for administration, e.g., oral, sublingual, nasal, or parenteral.

In preparing the compositions in oral dosage form, any of the usual media may be employed. For oral liquid preparations (e.g., suspensions, elixirs, and solutions), media containing for example, water, oils, alcohols, flavoring agents, preservatives, coloring agents and the like may be used. Carriers such as starches, sugars, diluents, granulating agents, lubricants, binders, disintegrating agents, and the like may be used to prepare oral solids (e.g., powders, capsules, pills, tablets, and lozenges). Controlled release forms may also be used. Because of their ease in administration, tablets, pills, and capsules represent the most advantageous oral dosage unit form, in which case solid carriers are obviously employed. If desired, tablets may be sugar coated or enteric coated by standard techniques.

In preparing the compositions of the invention, the above-described active ingredients may be combined with a

variety of non-essential ingredients which perform the functions described in the above description of dosage forms. Such non-essential ingredients may include in weight per lozenge: about 2 mg to about 10 mg biotin; about 1 mg to about 5 15 mg pantothenic acid; about 100 mg to about 300 mg calcium carbonate; about 0.01 mg to about 0.1 mg potassium iodide; about 5 to about 25 mg iron ortho phosphate; about 25 to about 100 mg magnesium oxide; about 1 to about 10 mg copper gluconate; about 2 to about 10 mg zinc oxide; about 2 mg to 10 about 15 mg manganese gluconate; about 5 mg to about 15 mg molybdenum yeast (where there is about 2 micrograms of molybdenum per gram of yeast or alternatively expressed as 2,000 ppm) [Redstar]; about 2 mg to about 20 mg chromium yeast (about 2,000 ppm) [Redstar]; about 5 to about 50 mg selenium 15 yeast (about 1,200 ppm) [Redstar]; about 2 mg to about 15 mg choline; and about 2 to about 15 mg inositol.

The following examples are illustrative only, and do not purport to limit the invention in any fashion.

EXAMPLE 1

20 The following components are co-administered to comprise a single dosage of the first class of compositions of the present invention.

Antioxidant component (2 lozenges)

| 25 | <u>Ingredient</u> | <u>Approximate</u> |
|----|----------------------------------|--------------------|
| | <u>Amount</u> | |
| | Vitamin A | 1,000 IU |
| | Vitamin C | 500 mg |
| | Vitamin E | 250 IU |
| | Selenium | 70 µg |
| 30 | Barley juice concentrate (20-1) | 80 mg |
| | Spinach juice concentrate (20-1) | 50 mg |

| | | |
|---|-------------------------------------|-------|
| | Alfalfa juice concentrate (20-1) | 50 mg |
| | Parsley juice concentrate (20-1) | 50 mg |
| | Artichoke juice concentrate (20-1) | 70 mg |
| | Carrot juice concentrate (20-1) | 60 mg |
| 5 | Cabbage juice concentrate (20-1) | 20 mg |
| | Strawberry juice concentrate (20-1) | 60 mg |
| | Papaya juice concentrate (20-1) | 40 mg |

Multi-vitamin component (2 lozenges)

| <u>Amount</u> | <u>Ingredient</u> | <u>Approximate</u> |
|--|---|--------------------|
| 5 | Vitamin A | 2,000 IU |
| | Vitamin C | 25 mg |
| | Vitamin E | 15 IU |
| | Selenium | 5.3 μ g |
| | Folic acid | 0.1 mg |
| 10 | Thiamine (B-1) | 0.5 mg |
| | Riboflavin | 0.5 mg |
| | Niacin | 7.5 mg |
| | Vitamin B-6 | 1.5 mg |
| | Vitamin B-12 | 2.15 mg |
| 15 | Biotin | 0.115 mg |
| | Pantothenic acid | 3.0 mg |
| | Calcium | 250 mg |
| | Phosphorous | 25 mg |
| | Iodine | 30 mg |
| 20 | Iron | 5.1 mg |
| | Magnesium | 50 mg |
| | Copper | 0.5 mg |
| | Zinc | 5 mg |
| | Manganese | 1.25 mg |
| 25 | Barley juice concentrate (approx. 20-1) | 80 mg |
| | Spinach juice concentrate (approx. 20-1) | 50 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 50 mg |
| | Parsley juice concentrate (approx. 20-1) | 50 mg |
| | Artichoke juice concentrate (approx. 20-1) | 70 mg |
| 30 | Carrot juice concentrate (approx. 20-1) | 40 mg |
| | Cabbage juice concentrate (approx. 20-1) | 60 mg |
| | Strawberry juice concentrate (approx. 20-1) | 60 mg |
| | Papaya juice concentrate (approx. 20-1) | 60 mg |
| | Apple juice concentrate (approx. 20-1) | 60 mg |
| Ginkgo biloba component (1 lozenge) | | |
| 35 | Ginkgo biloba extract (Westar Nutrition) | 60 mg |
| | Brown rice powder | 440 mg |
| Green barley component (1 lozenge) | | |
| | Green barley juice concentrate | 600 mg |
| | Malt dextrin | 150 mg |

40

EXAMPLE 2

The following components are co-administered to comprise

a

single dosage of the first class of compositions of the present invention.

45

Antioxidant component (2 lozenges)

| <u>Amount</u> | <u>Ingredient</u> | <u>Approximate</u> |
|---------------|---|--------------------|
| | Vitamin A | 1,000 IU |
| | Vitamin C | 500 mg |
| 5 | Vitamin E | 250 IU |
| | Selenium | 100 µg |
| | Barley juice concentrate (approx. 20-1) | 20 mg |
| | Spinach juice concentrate (approx. 20-1) | 50 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 50 mg |
| 10 | Parsley juice concentrate (approx. 20-1) | 70 mg |
| | Artichoke juice concentrate (approx. 20-1) | 70 mg |
| | Carrot juice concentrate (approx. 20-1) | 60 mg |
| | Cabbage juice concentrate (approx. 20-1) | 20 mg |
| | Strawberry juice concentrate (approx. 20-1) | 60 mg |
| 15 | Papaya juice concentrate (approx. 20-1) | 40 mg |

Multi-vitamin component (2 lozenges)

| <u>Amount</u> | <u>Ingredient</u> | <u>Approximate</u> |
|---------------|---|--------------------|
| | Vitamin A | 2,000 IU |
| 20 | Vitamin C | 25 mg |
| | Vitamin E | 15 IU |
| | Selenium | 5.3 µg |
| | Folic acid | 0.1 mg |
| | Thiamine (B-1) | 0.5 mg |
| 25 | Riboflavin | 0.5 mg |
| | Niacin | 7.5 mg |
| | Vitamin B-6 | 1.5 mg |
| | Vitamin B-12 | 2.15 mg |
| | Biotin | 0.115 mg |
| 30 | Pantothenic acid | 3.0 mg |
| | Calcium | 250 mg |
| | Phosphorous | 25 mg |
| | Iodine | 30 mg |
| | Iron | 5.1 mg |
| 35 | Magnesium | 50 mg |
| | Copper | 0.5 mg |
| | Zinc | 5 mg |
| | Manganese | 1.25 mg |
| | Barley juice concentrate (approx. 20-1) | 80 mg |
| 40 | Spinach juice concentrate (approx. 20-1) | 50 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 50 mg |
| | Parsley juice concentrate (approx. 20-1) | 50 mg |
| | Artichoke juice concentrate (approx. 20-1) | 70 mg |
| | Carrot juice concentrate (approx. 20-1) | 40 mg |
| 45 | Cabbage juice concentrate (approx. 20-1) | 60 mg |
| | Strawberry juice concentrate (approx. 20-1) | 60 mg |
| | Papaya juice concentrate (approx. 20-1) | 60 mg |
| | Apple juice concentrate (approx. 20-1) | 60 mg |

Ginkgo biloba component (1 lozenge)

| | | |
|----|--|-------|
| 50 | Ginkgo biloba extract (Westar Nutrition) | 60 mg |
|----|--|-------|

| | |
|---|--------|
| Brown rice powder (carrier) | 440 mg |
| Green barley component (1 lozenge) | |
| Green barley juice concentrate | 625 mg |
| Malt dextrin (carrier) | 100 mg |

5

EXAMPLE 3

The following composition falls within the first class of compositions of the present invention, and is in the form of a single lozenge for administration.

Multi-component lozenge A

| <u>Amount</u> | <u>Ingredient</u> | <u>Approximate</u> |
|---------------|---|--------------------|
| | Vitamin A | 3,000 IU |
| | Vitamin C | 500 mg |
| | Vitamin E | 250 IU |
| 15 | Selenium | 70 μ g |
| | Folic acid | 0.1 mg |
| | Thiamine (B-1) | 0.5 mg |
| | Riboflavin | 0.5 mg |
| | Niacin | 7.5 mg |
| 20 | Vitamin B-6 | 1.5 mg |
| | Vitamin B-12 | 2.15 mg |
| | Biotin | 0.115 mg |
| | Pantothenic acid | 3.0 mg |
| | Calcium | 250 mg |
| 25 | Phosphorous | 25 mg |
| | Iodine | 30 mg |
| | Iron | 5.1 mg |
| | Magnesium | 50 mg |
| | Copper | 0.5 mg |
| 30 | Zinc | 5 mg |
| | Manganese | 1.25 mg |
| | Barley juice concentrate (approx. 20-1) | 580 mg |
| | Spinach juice concentrate (approx. 20-1) | 50 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 50 mg |
| 35 | Parsley juice concentrate (approx. 20-1) | 50 mg |
| | Artichoke juice concentrate (approx. 20-1) | 70 mg |
| | Carrot juice concentrate (approx. 20-1) | 40 mg |
| | Cabbage juice concentrate (approx. 20-1) | 60 mg |
| | Strawberry juice concentrate (approx. 20-1) | 60 mg |
| 40 | Papaya juice concentrate (approx. 20-1) | 60 mg |
| | Apple juice concentrate (approx. 20-1) | 60 mg |
| | Ginkgo biloba extract | 60 mg |
| | Malt dextrin | 150 mg |

EXAMPLE 4

The following composition falls within the first class of compositions of the present invention, and is in the form of a single lozenge for administration.

Multi-component lozenge B

| 5 | <u>Ingredient</u> <u>Amount</u> | <u>Approximate</u> |
|----|---|--------------------|
| | Vitamin A | 14,000 IU |
| | Vitamin C | 530 mg |
| | Vitamin E | 170 IU |
| 10 | Vitamin D | 270 IU |
| | Selenium | 100 µg |
| | Folic acid | 0.2 mg |
| | Thiamine (B-1) | 1.7 mg |
| | Riboflavin | 3 mg |
| 15 | Niacin | 15 mg |
| | Vitamin B-6 | 7 mg |
| | Vitamin B-12 | 4.7 mg |
| | Biotin | 0.15 mg |
| | Pantothenic acid | 7.5 mg |
| 20 | Calcium | 250 mg |
| | Phosphorous | 50 mg |
| | Iodine | 75 µg |
| | Iron | 9 mg |
| | Magnesium | 104 mg |
| 25 | Copper | 1 mg |
| | Zinc | 10 mg |
| | Manganese | 2.5 mg |
| | Molybdenum | 50 µg |
| | Chromium | 100 µg |
| 30 | Choline | 11 mg |
| | Barley juice concentrate (approx. 20-1) | 50 mg |
| | Spinach juice concentrate (approx. 20-1) | 5 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 5 mg |
| | Parsley juice concentrate (approx. 20-1) | 5 mg |
| 35 | Artichoke juice concentrate (approx. 20-1) | 2 mg |
| | Carrot juice concentrate (approx. 20-1) | 1.5 mg |
| | Cabbage juice concentrate (approx. 20-1) | 10 mg |
| | Strawberry juice concentrate (approx. 20-1) | 2 mg |
| | Papaya juice concentrate (approx. 20-1) | 2 mg |
| 40 | Apple juice concentrate (approx. 20-1) | 2 mg |
| | Kiwi juice concentrate (approx. 20-1) | 2 mg |
| | Acorn Squash juice concentrate (approx. 20-1) | 2 mg |
| | Grapefruit juice concentrate (approx. 20-1) | 2 mg |
| | Celery juice concentrate (approx. 20-1) | 2 mg |
| 45 | Orange juice concentrate (approx. 20-1) | 2 mg |
| | Kale juice concentrate (approx. 20-1) | 2 mg |
| | Tomato juice concentrate (approx. 20-1) | 2 mg |
| | Lettuce juice concentrate (approx. 20-1) | 2 mg |
| | Banana juice concentrate (approx. 20-1) | 2 mg |
| 50 | Ginkgo biloba extract | 14 mg |
| | Maltodextrin | 150 mg |

EXAMPLE 5

A study was undertaken to evaluate the effect of the present invention on serum lipid profile, serum calcium levels, and serum sugar levels. The objectives of the study were to determine (1) whether oral intake of the composition results in increased levels of calcium ion in the human blood; (2) whether oral intake of the composition influences the levels of HDL in the lipid fraction distribution; and (3) whether oral intake of the composition influences the blood glucose levels.

A total of 50 subjects with ages between 45 and 65 years with abnormal lipid profiles were divided into 2 groups. One group (25 subjects) received placebo packages and ingested this twice a day, once in the morning and once in the evening. The other group (25 subjects) received a composition of the present invention which included two multi-vitamin lozenges, 1 antioxidant lozenge, 1 ginkgo biloba gelatin capsule, and 1 green barley lozenge, and ingested twice daily, once in the morning and once in the afternoon. The below-described results were compiled after a 2 month testing period. The identity of the lozenges was unknown by the subjects, and to the examiner (i.e., a double blind study). Blood serum (approximately 4 cc) was collected at the starting time and again after the completion of two months of usage. A fasting lipid profile was conducted on the plasma samples using a lipid fractionation panel automated system [Hewlett-Packard Co.]. In addition, measurements of electrolytes (including

calcium ion) and glucose levels were made using the Chem 18 automated system [Hewlett-Packard Co.] .

The results demonstrated (1) a statistically significant increase in the calcium ion levels for subjects using the first class of compositions of the present invention over those using the placebo (see Figure 1, showing the percentage increase in calcium over the placebo); (2) a statistically significant increase in the levels of HDL of about 35% was observed for subjects using the first class of compositions of the present invention over those using the placebo (see Figure 2, showing the percentage increase in HDL over the placebo); and (3) a statistically significant decrease in the levels of glucose of about 22% was observed for subjects using the first class of compositions of the present invention over those using the placebo (see Figure 3, showing the percentage decrease in blood glucose over the placebo).

EXAMPLE 6

The following composition falls within the second class of compositions of the present invention, and is in the form of a single lozenge for administration.

| | <u>Ingredient</u> | <u>Approximate</u> |
|----|---|--------------------|
| | <u>Amount</u> | |
| | Vitamin A (from beta carotene) | 5,000 IU |
| | Vitamin C | 500 mg |
| 5 | Vitamin E | 100 IU |
| | Selenium | 100 µg |
| | Barley juice concentrate (approx. 20-1) | 240 mg |
| | Spinach juice concentrate (approx. 20-1) | 250 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 290 mg |
| 10 | Parsley juice concentrate (approx. 20-1) | 270 mg |
| | Artichoke juice concentrate (approx. 20-1) | 270 mg |
| | Carrot juice concentrate (approx. 20-1) | 260 mg |
| | Cabbage juice concentrate (approx. 20-1) | 260 mg |
| | Strawberry juice concentrate (approx. 20-1) | 260 mg |
| 15 | Papaya juice concentrate (approx. 20-1) | 260 mg |

EXAMPLE 7

The following composition falls within the second class of compositions of the present invention, and is in the form of a single lozenge for administration.

| | | |
|----|---|--------------------|
| 20 | <u>Ingredient</u> | <u>Approximate</u> |
| | <u>Amount</u> | |
| | Vitamin A (from beta carotene) | 10,000 IU |
| | Vitamin C | 400 mg |
| | Vitamin E | 200 IU |
| 25 | Selenium | 150 µg |
| | Barley juice concentrate (approx. 20-1) | 260 mg |
| | Spinach juice concentrate (approx. 20-1) | 280 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 260 mg |
| | Parsley juice concentrate (approx. 20-1) | 260 mg |
| 30 | Artichoke juice concentrate (approx. 20-1) | 240 mg |
| | Carrot juice concentrate (approx. 20-1) | 260 mg |
| | Cabbage juice concentrate (approx. 20-1) | 250 mg |
| | Strawberry juice concentrate (approx. 20-1) | 250 mg |
| | Papaya juice concentrate (approx. 20-1) | 260 mg |

35

EXAMPLE 8

The following composition falls within the second class of compositions of the present invention, and is in the form of a single lozenge for administration.

| | <u>Ingredient</u> | | <u>Approximate</u> |
|----|---|--|--------------------|
| | <u>Amount</u> | | |
| | Vitamin A (from beta carotene) | | 10,000 IU |
| | Vitamin C | | 500 mg |
| 5 | Vitamin E | | 250 IU |
| | Selenium | | 100 μ g |
| | Barley juice concentrate (approx. 20-1) | | 280 mg |
| | Spinach juice concentrate (approx. 20-1) | | 250 mg |
| | Alfalfa juice concentrate (approx. 20-1) | | 250 mg |
| 10 | Parsley juice concentrate (approx. 20-1) | | 270 mg |
| | Artichoke juice concentrate (approx. 20-1) | | 270 mg |
| | Carrot juice concentrate (approx. 20-1) | | 260 mg |
| | Cabbage juice concentrate (approx. 20-1) | | 260 mg |
| | Strawberry juice concentrate (approx. 20-1) | | 260 mg |
| 15 | Papaya juice concentrate (approx. 20-1) | | 260 mg |

EXAMPLE 9

The following composition falls within the second class of compositions of the present invention, and is in the form of a single lozenge for administration.

| | <u>Ingredient</u> | | <u>Approximate</u> |
|----|---|--|--------------------|
| | <u>Amount</u> | | |
| 20 | Vitamin A (from beta carotene) | | 20,000 IU |
| | Vitamin C | | 1,000 mg |
| | Vitamin E | | 250 IU |
| 25 | Selenium | | 100 μ g |
| | Barley juice concentrate (approx. 20-1) | | 235 mg |
| | Spinach juice concentrate (approx. 20-1) | | 250 mg |
| | Alfalfa juice concentrate (approx. 20-1) | | 250 mg |
| | Parsley juice concentrate (approx. 20-1) | | 275 mg |
| 30 | Artichoke juice concentrate (approx. 20-1) | | 270 mg |
| | Carrot juice concentrate (approx. 20-1) | | 260 mg |
| | Cabbage juice concentrate (approx. 20-1) | | 260 mg |
| | Strawberry juice concentrate (approx. 20-1) | | 260 mg |
| | Papaya juice concentrate (approx. 20-1) | | 260 mg |

35 EXAMPLE 10

An experiment was undertaken to evaluate the effect of the second class of compositions on serum lipid profile, serum antioxidant levels, and plasma peroxide levels in normal healthy subjects. The objectives of the study were to

40 determine whether oral administration of the second class of compositions of the present invention would result in: (a) an

increase in serum antioxidant levels; (b) an increase in the level of HDL; and (c) a reduction in serum levels of oxidants.

A total of 10 healthy subjects between the ages of 19 and 23 years old were enrolled in a double blind cross over study.

5 In the first arm of the study, half the subjects received antioxidant tablets and the other half received a placebo matched tablet containing mineral oil for 4 weeks. Subsequent to this 4 week first arm of the study, the subjects were taken off of all tablets for 4 weeks. Then, the second arm of the
10 study began in which the subjects who were receiving the antioxidant tablets and those receiving the placebo from the first arm of the study switched.

Each subject took two tablets -- the first at 9:00 am and the second at 4:00 pm. There were no other dietary
15 restrictions, bearing in mind that all subjects were college students and had a fair awareness of their diet content.

Each subject had blood drawn at three specific times: before the study commenced (as a baseline); at the end of the first arm of the study; and at the end of the second arm of
20 the study. Blood samples were drawn at three different times of day during each period: 8:00 am (fasting levels, prior to the first dose); 12:00 pm (prior to lunch); and 4:00 pm (prior to dinner and to the second dose).

Blood samples were then subjected to CBC analysis with
25 differential electrolytes, liver function panel, and lipid fraction panel; peroxide level determination by horseradish peroxidase assay based on the method of Frew et al., Anal. Chem. Acta, 155:139-150 (1983), and vitamin A and E level

determination by SmithKline Beecham Clinical Laboratories, Los Angeles, CA.

The antioxidant tablets used were of the following composition:

| 5 | <u>Ingredient</u> <u>Amount</u> | <u>Approximate</u> |
|----|---|--------------------|
| | Vitamin A (from beta carotene) | 2,500 IU |
| | Vitamin C | 250 mg |
| | Vitamin E | 50 IU |
| 10 | Selenium | 50 µg |
| | Barley juice concentrate (approx. 20-1) | 120 mg |
| | Spinach juice concentrate (approx. 20-1) | 125 mg |
| | Alfalfa juice concentrate (approx. 20-1) | 145 mg |
| | Parsley juice concentrate (approx. 20-1) | 135 mg |
| 15 | Artichoke juice concentrate (approx. 20-1) | 135 mg |
| | Carrot juice concentrate (approx. 20-1) | 130 mg |
| | Cabbage juice concentrate (approx. 20-1) | 130 mg |
| | Strawberry juice concentrate (approx. 20-1) | 130 mg |
| | Papaya juice concentrate (approx. 20-1) | 130 mg |

20 Placebo tablets contained mineral oil. Each of these tablet were ingested twice daily as per the schedule described above.

Data are expressed as averages of groups compared to placebo with each individual acting as their own placebo (since each subject underwent both a test arm and placebo arm
25 of the study). Significance was determined using paired Student's t-test for all data except beta-carotene where unpaired Student's t-test was employed. For beta-carotene, data was collected from 5 subjects only in each arm of the study.

30 The results demonstrated that at fasting levels, 80 percent of the subjects demonstrated a 10 percent reduction of total plasma oxidants at a 99 percent confidence level over placebo during intake of antioxidant vitamins. Measurements for oxidants obtained later during the day showed that only 50
35 and 60 percent of the subjects demonstrated a decrease for the

noon and 4:00 pm samples respectively, presumably because of interference of food substances absorbed and released into the plasma.

Ninety percent of the subjects showed a 19, 37, and 31 percent increase of vitamin E levels at confidence levels of 82, 99.9, and 99 percent for fasting, noon, and 4:00 pm samples respectively. This implies that endogenous vitamin E levels can be increased by antioxidant supplementation. Also, the relatively low fasting level is boosted after the 8:00 am dose by about 37 percent. This implies that the fasting level increase of 19 percent may have been lower if only the daily 8:00 am dosage was used.

Eighty percent of the subjects demonstrated a 46 percent increase in levels of beta-carotene at a 93 percent confidence level at 4:00 pm. However, this increase appeared to persist in only 20 percent of subjects at fasting and noon levels.

The maximum increase in vitamin A levels, 35 percent, was demonstrated at 4:00 pm with a 98 percent confidence level. The fasting and noon level increases were 14 and 11 percent for 50 and 30 percent of the subjects respectively.

Seventy percent of the subjects demonstrated a 48, 41, and 73 percent increase in serum HDL with a 97, 92, and 99.5 confidence level at fasting, noon, and 4:00 pm levels respectively. One subject outside of the study was followed for 1.5 years and continued to demonstrate a 50 percent increase in HDL levels while continuing oral intake of the antioxidants.

Clinical data presented in figures 4-8 demonstrate that those who took the daily dosage of the antioxidant composition described above compared to those taking the placebo have increased levels of vitamin A (see Fig. 4), increased levels of vitamin E (see Fig. 5), increased levels of beta-carotene (see Fig. 6), decreased levels of oxidants in blood serum (see Fig. 7), and increased levels of HDL (see Fig. 8).

Numerous modifications and variations of the present invention are included in the above-identified specification and are expected to be obvious to one of skill in the art. It is also intended that the present invention cover modifications and variations of the compositions and methods for using them to accomplish their claimed uses within the scope of the appended claims and their equivalents.

WHAT IS CLAIMED IS:

1. A nutritional supplement comprising: an antioxidant component comprising approximately 1,000 IU to approximately 10,000 IU vitamin A, approximately 200 IU to approximately 500 IU vitamin E, approximately 100 mg to approximately 500 mg vitamin C, and approximately 5 μ g to approximately 75 μ g selenium, and a first juice concentrate, a green barley component comprising green barley extract, a ginkgo component comprising ginkgo biloba extract, and a multi-vitamin and mineral component.

2. The nutritional supplement of claim 1, wherein the first juice concentrate comprises a plurality of juice concentrates selected from the group consisting of acorn squash, alfalfa, apple, artichoke, avocado, bananas, broccoli, brussels sprouts, cabbage, cantaloupe, carrot, cauliflower, celery, collard greens, grapefruit, green leek, kale, kiwi fruit, lettuce, onion, papaya, parsley, potato, prune, spinach, strawberry, sweet potato, swiss chard, and tomato juice concentrates.

3. The nutritional supplement of claim 1, wherein the vitamin A, the vitamin E, the vitamin C, the selenium, and the first juice concentrate form two antioxidant lozenges, each lozenge having a preferred weight of between approximately 1,000 mg and approximately 2,000 mg.

4. The nutritional supplement of claim 3, wherein the total weight of the first juice concentrate is between approximately 30% to approximately 80% of the total weight of each antioxidant lozenge.

5 5. The nutritional supplement of claim 3, wherein the total weight of the combination of the vitamin C, the vitamin A, the vitamin E, and the selenium is between about 10% to about 50% of the total weight of each antioxidant lozenge.

10 6. The nutritional supplement of claim 3, wherein the first juice concentrate has a concentration of at least 10 times that of native juice in the unconcentrated form.

15 7. The nutritional supplement of claim 2, wherein each first juice concentrate selected from the group of juice concentrates comprises between about 5% to about 25% of the weight of the total juice concentrate.

20 8. The nutritional supplement of claim 1, wherein the multi-vitamin and mineral component comprises vitamins and minerals selected from the group consisting of vitamin A, vitamin C, vitamin D, vitamin E, folic acid, thiamine (B-1), riboflavin, niacin, vitamin B-6, vitamin B-12, biotin, zinc, manganese, and selenium.

9. The nutritional supplement of claim 8, wherein the multi-vitamin and mineral component is derived from a non-juice source.

10. The nutritional supplement of claim 8, wherein the multi-vitamin and mineral component comprises a second juice concentrate is selected from the group consisting of: acorn squash, alfalfa, apple, artichoke, avocado, bananas, broccoli, brussels sprouts, cabbage, cantaloupe, carrot, cauliflower, celery, collard greens, grapefruit, green leek, green barley, kale, kiwi fruit, lettuce, onion, papaya, parsley, potato, prune, spinach, strawberry, sweet potato, swiss chard, and tomato juice concentrates.

11. The nutritional supplement of claim 9 or claim 10, wherein the multi-vitamin and mineral component forms two multi-vitamin and mineral lozenges.

12. The nutritional supplement of claim 11, wherein the preferred weight of each multi-vitamin and mineral lozenge is between approximately 750 mg to approximately 1,500 mg.

13. The nutritional supplement of claim 11, wherein the multi-vitamin and mineral component comprises second juice concentrates comprising between approximately 4% to approximately 25% of the total weight of the multi-vitamin and mineral lozenge.

14. The nutritional supplement of claim 11, wherein the multi-vitamin and mineral component comprises vitamins and minerals derived from a source other than from a juice concentrate and comprising about 10% to about 90% of the total weight of the multi-vitamin and mineral component.

15. The nutritional supplement of claim 11, wherein each multi-vitamin and mineral lozenge comprises an amount of vitamin A between about 1,000 IU to about 10,000 IU, an amount of vitamin C between about 10 mg to about 200 mg, an amount of vitamin D between about 10 IU to about 1,000 IU, an amount of vitamin E between about 5 IU to about 50 IU, an amount of folic acid between about 0.03 mg to about 1 mg, an amount of thiamine (B-1) between about 0.15 mg to about 0.75 mg, an amount of riboflavin between about 0.01 mg to about 5.0 mg, an amount of niacin between about 1.0 mg to 100 mg, an amount of vitamin B-6 between about 1.0 mg to about 10.0 mg, an amount of vitamin B-12 between about 1.0 mg to about 10.0 mg, an amount of biotin between about 0.10 mg to 1.00 mg, an amount of zinc between about 1.0 mg to about 10.0 mg, an amount of manganese between about 1.0 mg to about 10.0 mg, and an amount of selenium between about 5 μ g to about 20 μ g.

16. The nutritional supplement of claim 1, wherein the green barley extract component comprises, by weight percent, between approximately 60% to approximately 90% green barley juice concentrate.

17. The nutritional supplement of claim 16, wherein the green barley extract component forms one green barley extract lozenge.

18. The nutritional supplement of claim 17, wherein the weight of the green barley extract lozenge is approximately 600 mg to approximately 1,000 mg.

19. The nutritional supplement of claim 1, wherein the ginkgo biloba extract component comprises, by weight percent, approximately 5% to approximately 35% ginkgo biloba extract.

20. The nutritional supplement of claim 19, wherein the ginkgo biloba extract component forms one ginkgo biloba extract lozenge.

21. The nutritional supplement of claim 20, wherein the weight of the ginkgo biloba extract lozenge is from approximately 400 mg to approximately 750 mg.

22. A nutritional supplement comprising: two antioxidant lozenges, each comprising about 1,000 IU vitamin A, about 500 mg vitamin C, about 250 IU vitamin E, about 70 μ g selenium, about 80 mg green barley juice concentrate (approx. 20-1), about 50 mg spinach juice concentrate (approx. 20-1), about 50 mg alfalfa juice concentrate (approx. 20-1), about 50 mg parsley juice concentrate (approx. 20-1), about 70 mg artichoke juice concentrate (approx. 20-1), about 60 mg carrot

juice concentrate (approx. 20-1), about 20 mg cabbage juice concentrate (approx. 20-1), about 60 mg strawberry juice concentrate (approx. 20-1), and about 40 mg papaya juice concentrate (approx. 20-1); two multi-vitamin lozenges, each
5 comprising about 2,000 IU vitamin A, about 25 mg vitamin C, about 15 IU vitamin E, about 5.3 µg selenium, about 0.1 mg folic acid, about 0.5 mg thiamine (B-1), about 0.5 mg riboflavin, about 7.5 mg niacin, about 1.5 mg vitamin B-6, about 2.15 mg vitamin B-12, about 0.115 mg biotin, about 3.0
10 mg pantothenic acid, about 250 mg calcium, about 25 mg phosphorous, about 30 mg iodine, about 5.1 mg iron, about 50 mg magnesium, about 0.5 mg copper, about 5.0 mg zinc, about 1.25 mg manganese, about 80 mg green barley juice concentrate (approx. 20-1), about 50 mg spinach juice concentrate (approx.
15 20-1), about 50 mg alfalfa juice concentrate (approx. 20-1), about 50 mg parsley juice concentrate (approx. 20-1), about 70 mg artichoke juice concentrate (approx. 20-1), about 40 mg carrot juice concentrate (approx. 20-1), about 60 mg cabbage juice concentrate (approx. 20-1), about 60 mg strawberry juice
20 concentrate (approx. 20-1), about 60 mg papaya juice concentrate (approx. 20-1), and about 60 mg apple juice concentrate (approx. 20-1); a ginkgo biloba lozenge comprising about 60 mg ginkgo biloba extract [Westar Nutrition] and about 440 mg Brown rice powder; and a green barley lozenge
25 comprising about 600 mg green barley juice concentrate and 150 mg malt dextrin.

23. A nutritional supplement comprising: two antioxidant lozenges, each comprising about 1,000 IU vitamin A, about 500 mg vitamin C, about 250 IU vitamin E, about 100 μ g selenium, about 20 mg green barley juice concentrate (approx. 20-1),
5 about 50 mg spinach juice concentrate (approx. 20-1), about 50 mg alfalfa juice concentrate (approx. 20-1), about 70 mg parsley juice concentrate (approx. 20-1), about 70 mg artichoke juice concentrate (approx. 20-1), about 60 mg carrot juice concentrate (approx. 20-1), about 20 mg cabbage juice
10 concentrate (approx. 20-1), about 60 mg strawberry juice concentrate (approx. 20-1), and about 40 mg papaya juice concentrate (approx. 20-1); two multi-vitamin lozenges, each comprising about 2,000 IU vitamin A, about 25 mg vitamin C, about 15 IU vitamin E, about 5.3 μ g selenium, about 0.1 mg
15 folic acid, about 0.5 mg thiamine (B-1), about 0.5 mg riboflavin, about 7.5 mg niacin, about 1.5 mg vitamin B-6, about 2.15 mg vitamin B-12, about 0.115 mg biotin, about 3.0 mg pantothenic acid, about 250 mg calcium, about 25 mg phosphorous, about 30 mg iodine, about 5.1 mg iron, about 50
20 mg magnesium, about 0.5 mg copper, about 5.0 mg zinc, about 1.25 mg manganese, about 80 mg green barley juice concentrate (approx. 20-1), about 50 mg spinach juice concentrate (approx. 20-1), about 50 mg alfalfa juice concentrate (approx. 20-1), about 50 mg parsley juice concentrate (approx. 20-1), about 70
25 mg artichoke juice concentrate (approx. 20-1), about 40 mg carrot juice concentrate (approx. 20-1), about 60 mg cabbage juice concentrate (approx. 20-1), about 60 mg strawberry juice concentrate (approx. 20-1), about 60 mg papaya juice

concentrate (approx. 20-1), and about 60 mg apple juice concentrate (approx. 20-1); a ginkgo biloba lozenge comprising about 60 mg ginkgo biloba extract [Westar Nutrition] and about 440 mg brown rice powder; and a green barley lozenge comprising about 625 mg green barley juice concentrate and 100 mg malt dextrin.

24. A nutritional supplement comprising: an antioxidant component comprising about 3,000 IU vitamin A, about 500 mg vitamin C, about 250 IU vitamin E, about 70 μ g selenium, about 50 mg spinach juice concentrate (approx. 20-1), about 50 mg alfalfa juice concentrate (approx. 20-1), about 50 mg parsley juice concentrate (approx. 20-1), about 70 mg artichoke juice concentrate (approx. 20-1), about 40 mg carrot juice concentrate (approx. 20-1), about 60 mg cabbage juice concentrate (approx. 20-1), about 60 mg strawberry juice concentrate (approx. 20-1), about 60 mg papaya juice concentrate (approx. 20-1), and about 60 mg apple juice concentrate (approx. 20-1); a multi-vitamin and mineral component comprising about 0.1 mg folic acid, about 0.5 mg thiamine (B-1), about 0.5 mg riboflavin, about 7.5 mg niacin, about 1.5 mg vitamin B-6, about 2.15 mg vitamin B-12, about 0.115 mg biotin, about 3.0 mg pantothenic acid, about 250 mg calcium, about 25 mg phosphorous, about 30 mg iodine, about 5.1 mg iron, about 50 mg magnesium, about 0.5 mg copper, about 5.0 mg zinc, and about 1.25 mg manganese; a green barley component comprising about 580 mg green barley juice concentrate (approx. 20-1); and a ginkgo biloba extract

component comprising about 60 mg ginkgo biloba extract [Westar Nutrition] and about 150 mg malt dextrin.

25. A nutritional supplement comprising: an antioxidant component comprising about 14,000 IU vitamin A, about 530 mg
5 vitamin C, about 170 IU vitamin E, about 270 IU vitamin D, about 100 μ g selenium, about 5 mg spinach juice concentrate (approx. 20-1), about 5 mg alfalfa juice concentrate (approx. 20-1), about 5 mg parsley juice concentrate (approx. 20-1), about 2 mg artichoke juice concentrate (approx. 20-1), about
10 1.5 mg carrot juice concentrate (approx. 20-1), about 10 mg cabbage juice concentrate (approx. 20-1), about 2 mg strawberry juice concentrate (approx. 20-1), about 2 mg papaya juice concentrate (approx. 20-1), about 2 mg apple juice concentrate (approx. 20-1), about 2 mg kiwi juice concentrate
15 (approx. 20-1), about 2 mg acorn squash juice concentrate (approx. 20-1), about 2 mg grapefruit juice concentrate (approx. 20-1), about 2 mg celery juice concentrate (approx. 20-1), about 2 mg orange juice concentrate (approx. 20-1), about 2 mg kale juice concentrate (approx. 20-1), about 2 mg
20 tomato juice concentrate (approx. 20-1), about 2 mg lettuce juice concentrate (approx. 20-1), and about 2 mg banana juice concentrate (approx. 20-1); a multi-vitamin and mineral component comprising about 0.2 mg folic acid, about 1.7 mg thiamine (B-1), about 3 mg riboflavin, about 15 mg niacin,
25 about 7 mg vitamin B-6, about 4.7 mg vitamin B-12, about 0.15 mg biotin, about 7.5 mg pantothenic acid, about 250 mg calcium, about 50 mg phosphorous, about 75 μ g iodine, about

9 mg iron, about 104 mg magnesium, about 1 mg copper, about 10 mg zinc, and about 2.5 mg manganese; a green barley component comprising about 50 mg green barley juice concentrate (approx. 20-1); and a ginkgo biloba extract component comprising about 14 mg ginkgo biloba extract [Westar Nutrition], about 150 mg maltodextrin, about 50 μ g molybdenum, about 100 μ g chromium, and about 11 mg choline.

26. A method for preparing the nutritional supplement of claim 1 or claim 25, comprising admixing the components with a suitable carrier.

27. A method of increasing levels of high density lipoprotein (HDL) in human blood plasma comprising administering daily the nutritional supplement of claim 1, claim 22, claim 23, claim 24, or claim 25.

28. A method of decreasing the concentration of free radicals in human blood plasma comprising administering daily the nutritional supplement of claim 1, claim 22, claim 23, claim 24, or claim 25.

29. A method of decreasing blood glucose levels comprising administering daily the nutritional supplement of claim 1, claim 22, claim 23, claim 24, or claim 25.

30. A method of increasing calcium ion concentration in human blood plasma comprising administering daily the

nutritional supplement of claim 1, claim 22, claim 23, claim 24, or claim 25.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/11243

| A. CLASSIFICATION OF SUBJECT MATTER | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|-------|---|--|-------|--|--|-------|--|---|-------|---|--|--|--|--|--|--|
| IPC(6) : A01N 65/00; A61K 9/20; A23L 1/00, 1/30, 2/00 US CL : 424/195.1, 464; 426/590, 599, 615, 648 According to International Patent Classification (IPC) or to both national classification and IPC | | | | | | | | | | | | | | | | | | | | |
| B. FIELDS SEARCHED | | | | | | | | | | | | | | | | | | | | |
| Minimum documentation searched (classification system followed by classification symbols) U.S. : 424/195.1, 464; 426/590, 599, 615, 648 | | | | | | | | | | | | | | | | | | | | |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched | | | | | | | | | | | | | | | | | | | | |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) APS | | | | | | | | | | | | | | | | | | | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | | | | | | | | | | | | | | | | | | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. | | | | | | | | | | | | | | | | | | |
| Y | US 5,290,605 A (SHAPIRA) 01 March 1994, see especially columns 2-6, and claims. | 1-22, 26, and 32 | | | | | | | | | | | | | | | | | | |
| Y | US 4,753,816 A (VINK et al.) 28 June 1988, see especially columns 2-4. | 1-22, 26, and 32 | | | | | | | | | | | | | | | | | | |
| Y,P | US 5,571,441 A (ANDON et al.) 05 November 1996, see especially column 12, Example V. | 1-22, 26, and 32 | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex. | | | | | | | | | | | | | | | | | | | | |
| <table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>* I -</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>* A - document defining the general state of the art which is not considered to be of particular relevance</td> <td>* X -</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>* E - earlier document published on or after the international filing date</td> <td>* Y -</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>* L - document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>* G -</td> <td>document member of the same patent family</td> </tr> <tr> <td>* O - document referring to an oral disclosure, use, exhibition or other means</td> <td></td> <td></td> </tr> <tr> <td>* P - document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table> | | | * Special categories of cited documents: | * I - | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention | * A - document defining the general state of the art which is not considered to be of particular relevance | * X - | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone | * E - earlier document published on or after the international filing date | * Y - | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art | * L - document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | * G - | document member of the same patent family | * O - document referring to an oral disclosure, use, exhibition or other means | | | * P - document published prior to the international filing date but later than the priority date claimed | | |
| * Special categories of cited documents: | * I - | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention | | | | | | | | | | | | | | | | | | |
| * A - document defining the general state of the art which is not considered to be of particular relevance | * X - | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone | | | | | | | | | | | | | | | | | | |
| * E - earlier document published on or after the international filing date | * Y - | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art | | | | | | | | | | | | | | | | | | |
| * L - document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | * G - | document member of the same patent family | | | | | | | | | | | | | | | | | | |
| * O - document referring to an oral disclosure, use, exhibition or other means | | | | | | | | | | | | | | | | | | | | |
| * P - document published prior to the international filing date but later than the priority date claimed | | | | | | | | | | | | | | | | | | | | |
| Date of the actual completion of the international search 13 AUGUST 1997 | | Date of mailing of the international search report 29 AUG 1997 | | | | | | | | | | | | | | | | | | |
| Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 | | Authorized officer CHRISTOPHER TATE Telephone No. (703) 308-0196 | | | | | | | | | | | | | | | | | | |